DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Office of the Regional Food and Drug Director
Food and Drug Administration
Southwest Region
4040 North Central Expressway, Suite 900
Dallas, Texas 75204-3158
Telephone: 214-253-4901
Facsimile: 214-253-4960

WARNING LETTER

March 31, 2004

Via Federal Express—Next Day

Marti Schall
Regulatory Compliance Specialist
Source One Healthcare Technologies
8020 Tyler Boulevard
Mentor, OH 44060

Re: Field Test Number GI-72275

Dear Ms. Schall:

On March 10, 2004, a representative from the Food and Drug Administration (FDA) conducted a field test of the certified diagnostic x-ray system at the following facility:

Name of Facility: [redacted]
Address: [redacted]
City, State Zip: [redacted]

X-Ray Control Manufacturer: General Electric
X-Ray Control Model/ Serial No.: 46-240483G1/53929WK5
Room No.: R/F 1

Our records indicate that your firm assembled this system (FDA-2579; D901839) on August 18, 2003, and we tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (21 C.F.R. §§ 1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This letter confirms the telephone notification on March 10, 2004 to your firm from the facility. During this telephone call, it was requested that you immediately correct the following serious non-compliances with the performance standard:

- At the technique factors of 90 kVp, and 22.4 mA, the automatic fluoroscopic entrance exposure rate was measured to be 35.2 R/min. This exceeds the limit of 10 R/min specified in 21 CFR 1020.32(d).

- At the technique factors of 80 kVp, and 37.3 mA, the manual fluoroscopic entrance exposure rate was measured to be 39.8 R/min. This exceeds the limit of 10 R/min specified in 21 CFR 1020.32(d).

We request that you, as the responsible assembler, investigate the deviations from the performance standard and/or the defects listed above in accordance with 21 C.F.R. §§ 1003 and 1004, as follows:

1. If you determine that the deviation and/or defect is caused by improper assembly or installation, you should correct the deviation and/or defect *at no charge* to the user by either repairing the system, replacing it, or refunding the cost.

2. If you determine that the deviation and/or defect is caused by the factory-based manufacturer, you should notify the manufacturer of the deviation and/or defect and send documentation of such notification to this office.

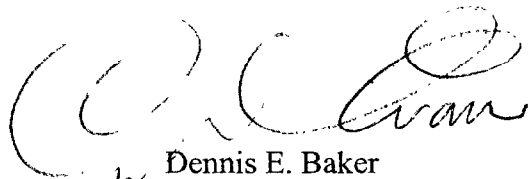
3. If you can establish that the system is compliant, that the alleged deviation and/or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence to this office in accordance with 21 C.F.R. § 1003.11(a)(3) within 15 working days of receipt of this letter.

You are requested to report the results of your investigation and follow-up action to this office within 15 working days of the receipt of this letter. Your response should include the date that the corrective actions were completed, and a copy of the service record and/or other supportive documents. Failure to respond constitutes a violation of the Act, Sections 538(a)(2) and 538(a)(4) of Sub-chapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Failure to promptly correct this violation can result in regulatory action being initiated by FDA without further notice. These actions include seizure, injunction, and the imposition of civil penalties as provided for in Section 539 of the Act. Persons violating Section 538 of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

Your response should be sent to Deborah M. McGee, Compliance Officer, Food and Drug Administration, 4040 N. Central Expressway, Suite 900, Dallas, TX 75204. If you have any questions, please contact Ms. McGee at (214) 253-4935.

Sincerely,



for Dennis E. Baker
Regional Food and Drug Director

cc: